REMARKS/ARGUMENTS

Rejection under 35 U.S.C. §101

Claims 1-2 are being rejected under 35 USC §101 as being directed to non-statutory subject matter, the office action stating that the claimed invention fails to produce a useful, tangible, and concrete result. Applicant respectfully submits that the claimed invention is directed to statutory subject matter under the law and produces a useful, tangible and concrete result, and not a mere, subjective assessment. for the following reasons.

The U.S. Supreme Court acknowledged that Congress, through its legislative history, intended statutory subject matter to "include anything under the sun that is made by man." *See Diamond v. Chakrabarty,* 447 U.S. 303, 309; 206 U.S.P.Q. 193, 197 (1980). The U.S. Supreme Court has specifically identified categories of non-statutory subject matter, including abstract ideas. *See Diamond Diehr,* 450 U.S. 175; 209 U.S.P.Q. 1 (1981). However, when an abstract idea is reduced to a practical application, the abstract idea no longer stands alone if the practical application of the abstract idea produces certain useful, concrete, and tangible results, thus satisfying the requirements of 35 U.S.C. §101. *In re: Alappat*, 31 U.S.P.Q. 2d 1545, 1558 (Fed. Circ. 1994); *State Street Bank & Trust Co. v. Signature Financial Group Inc.*, 470 U.S.P.Q. 2d 1596, 1601-02 (Fed. Circ. 1998). For example, a predictive model may be used to optimize return on marketing investment by ranking consumers according to their predicted response to promotions, and then mailing promotional materials only to those consumers who are most likely

to respond and generate revenue. *Ex parte Edwin Peter Dawson Pednault*, Appeal No. 2002-0308 (BPAI), *unpubl'd. op.*

Claim 1 of the Invention is rejected for reciting the manipulation of abstract ideas, although the recited steps produce a transformation of such abstract ideas into a diagnostic tool, a single pain index score giving a tangible, repeatable and reliable measurement and predictor of the effect of somatization for each patient. Specifically, the Invention transforms the industry standard set of declarative statements (developed by the MMPI personality test for the diagnosis of psychopathology and personality attitudes) into a single diagnostic tool. *See* Specification, pages 4, 8 and 9 and Fig. 1. In particular, Claim 1 specifies that the recorded attributes of the patients, the patient responses to the MMPI, are configured by the Invention's patient response analysis into certain validity factor scales and clinical factor scales, such configuration affecting a patentable subject matter as a change in the natural world because patients' attitudes are not naturally configured or arranged in this manner in the natural world, as confirmed by Hamlin, et al, "Predicting Surgical Outcome for Pain Relief and Return to Work," Specification, p. 2. *See* Gregory A. Stobbs, Business Method Patents, Aspen Publishers, Inc. (2002), p. 63.

The processes used to extract, modify, and concentrate natural agencies constitute the invention. *Le Roy v. Tatham*, 55 U.S. 156, 173 (1852). The claimed invention, as identified in the Specification extracts, modifies, and concentrates a property of nature (the patient's responses to the declarative statements of patient symptoms indicating psychopathology and personality attitudes), not merely identifying or naming that property of nature. The essence of the claimed

Invention is providing a reliable predictor of somatization to assist physicians with patients exhibiting symptoms of medical disorder, by identifying and quantifying psychological problems, where natural symptoms do not correspond with diagnostic studies and/or physical symptoms. Specification, p. 2.

The Invention's configuration or scheduled steps for analyzing the declarative statements leaves the abstract domain and enter the concrete world of the artificial domain when the analysis is recorded. Although many of the recited steps themselves involve manipulation of abstract ideas they are affected by an artificial (man-made) agency, thereby making the subject matter statutory. *See* Stobbs, *supra.*

Claims 1 and 2 of the Invention recite several recording steps that result in creation of an artificial entity - a Pain Index Score, which did not exist before in the artificial world. The agency responsible for effecting this change is Claim 1 having the two steps of: (1) recording the patient attribute responses to the declarative statements on the response sheets and (2) scoring the responses on the validity and clinical factor sheets, and providing for a recordable Pain Index Score and a Probability Equation Score set down on the Paindex® outcome analysis, thereby creating a predictable and repeatable artificial, assessment score.

Until set down in the Paindex® outcome analysis, the patient responses were in the abstract domain. The Pain Index Score and the Paindex® outcome analysis gave substance to the analysis, as readily recognized by the industry. Hamlin, et al. The Invention, while relying on "low technology" analytical scoring procedure, produces a valuable tangible tool with profound

importance. *See* U.S. Patent #5,278,750 to Kaneko et al, entitled "Production Schedule Making Method," of a schedule for something inherently abstract, but entering the artificial domain when written down or recorded.

Claims 1 and 2 of the Invention recite a method of diagnostic test or system for identifying and quantifying certain psychological and behavioral, or clinical, factors having a critical bearing on decisions by physicians for medical treatment of patients and predicting patient problems that can occur post-operatively due to somatization. The method transforms scores representing psychological/psychiatric assessments, into a final, repeatable score using a computational model of a series of mathematical calculations or data set. The computational model is programmed to transform the data, which represents discrete personality scores, into a final recordable score, constituting a practical application of mathematical algorithms, formulae, or calculations producing "a useful, concrete, and tangible result," i.e., the final pain index score upon which physicians can make medical, treatment decisions. Specification, pp. 1-5. *See State Street,* 149 F. 3d at 1374,-75, 47, U.S.P.Q. 2d at 1602. Under *State Street*, a process employing an abstract idea may be patentable subject matter, even though the abstract idea would not, by itself, be entitled to such protection.

The invention does not claim the underlying mathematical algorithms or the psychological/psychiatric declarative statements nor preclude their use in any other applications; rather, the Invention applies its method to produce a useful, concrete, and tangible result (without preempting other uses of the mathematical or psychological, psychiatric assessment principles),

to predict the impact of clinical factors on surgical treatment or outcome for a patient. Specification, p. 5. *See AT&T Corp. v. Excel Comm. Inc.,* 50 U.S.P.Q. 2d 1447, 1452 (Fed. Circ. 1999). Therefore, while an abstract idea by itself never satisfies the requirements of 35 U.S.C. §101, an abstract idea when practically applied to produce a useful, concrete, and tangible result does satisfy the utility requirement under 35 U.S.C. §101. Even if some or all the steps of a method or process can be carried out with the aid of the human mind, or because it is necessary for one performing the method or process to think or analyze, the method or process would remain statutory so long as a useful, concrete, and tangible result is produced. *See In re Musgrove,* 431 F. 2 d 882, 893; 167 U.S.P.Q. 280, 289 (C.C.P.A. 1970).

The claims recite several recording steps that result in the creation of an artificial entity - a pain index score, as a predictor of somatization. The process of writing down and establishing the pain index score, itself, affects a change in the artificial world because now something exists in the artificial world that did not exist before. The agency responsible for affecting this change is the act of recording the various scores on the scoring sheets. Specification, pp. 11-13, and FIGS. 2-12. The pain index score, an artificial element, gave substance to the responses of the patient as statutory subject matter. Stobbs, *supra* at 65-66.

Claim 1 is also rejected in the Office Action because it appears to lack practical utility. Under *Diehr, supra,* the Supreme Court requires that the examiner look at the claimed invention as a whole and compare any asserted utility with the claimed invention to determine whether the asserted utility is accomplished. The utility may be expressly recited in the claims or inferred; if

not asserted in a written description, it must be well established. Finally, a specific, substantial, and credible utility must be accomplished.

The article by Hamlin, et al. (used in the Office Action as rejection for other reasons herein) leaves little doubt that there is a well-established utility in the case of the Invention, which successfully solves the problem expressly recited in its Specification, pages 1-7 and Claim 1. As noted in the Specification, industry failure in predicting outcome for treatment aimed at pain relief has been one of the most costly problems facing the health care delivery system today. Prior to the Applicant's invention there is almost no support in medical literature for psychological/psychiatric assessment as a reliable predictor of somatization and the surgical outcome or other medical treatment for the relief of pain. *See* Hamlin, et al. As set forth in the Specification, the present Invention specifically identifies and quantifies psychological problems and predicts, to a high statistical probability (i.e., demonstrating a substantial and credible utility), the probability of patient pain relief, where symptoms do not correspond with diagnostic studies and/or physical symptoms. Hamlin, et al, at p. 258. In other words, the Invention provides a very practical utility, achieving a very useful, concrete, and tangible result; a change of abstract ideas from the natural world into an artificial patentable entity.

The Office Action asserts that the method of diagnosing a probability does not produce concrete, substantially repeatable results. However, it is due to his success in inventing a method with a predictable or repeatable result that induced the Applicant to patent this method Invention. *See* Specifications, pages 2, and 4-6. As set forth above, other experts in the industry have noted

that the Applicant had already achieved a high statistical probability regarding patient pain relief with his prior work where patient symptoms did not correspond with diagnostic studies and/or physical symptoms (which constitute the set of abstract ideas). Therefore, the Invention discloses a specific and substantial utility for a very practical, particular purpose, considered credible by individuals of ordinary skill in the art. *See* Hamlin et al. MPEP §2107.

The present Invention overcomes the shortcomings of earlier related art and the Applicant's earlier failure to more accurately predict the probability of pain relief by medical treatment, due to a lack of balance between the sensitivity scores and the specificity scores to achieve an acceptable predictability result. Applicant accomplishes this in the present invention through the recognition and quantification of an additional E factor, another advantage of the present Invention, closing the gap between sensitivity and specificity scores, which balanced the testing method of the present Invention and proved the predictive accuracy to the middle to high ninety percent (90 %), as independently observed by medical physicians, verifying that the Applicant's Invention is substantially repeatable. Specification, p. 6. Therefore, the result found by this method Invention is not speculative and would not require further undue experimentation to produce concrete results, as demonstrated above, satisfying the test of *In re Wamerdam*, 31 U.S.P.Q. 2d 1754 (Fed. Circ. 1994), and *In re Schrader*, 30 U.S.P.Q. 2d 1445 (Fed. Cir. 1994).

Applicant respectfully submits that the claimed invention is directed to statutory subject matter under the law and produces a useful, tangible and concrete result for the reasons set forth.

Rejection under 35 U.S.C. §112, first paragraph

Claims 1 and 2 are being rejected under 35 U.S.C. §112, first paragraph, for not being supported by either a specific and substantial asserted utility or a well-established utility, directed to the lack of substantial repeatability.

As pointed out above, and reasserting those arguments set forth above, the Applicant asserts that it was his success in inventing a method with a predictable or repeatable result that induced the Applicant to go to patent. *See* Specifications, pages 2, and 4-6. The Hamlin, et al article is highly probative of the Applicant's assertions of credibility, as evidence of utilities taught in the closest prior art. Other experts in the industry noted that the Applicant had already achieved a high statistical probability regarding patient pain relief with his prior work where patient symptoms did not correspond with diagnostic studies and/or physical symptoms (which constitute the set of abstract ideas). The present Invention overcomes the shortcomings of earlier related art and the Applicant's earlier failure to more accurately predict the probability of pain relief by medical treatment, due to what he identified as a lack of balance between the sensitivity scores and the specificity scores to achieve an acceptable predictability result, through the recognition and quantification of an additional E factor, ego integrative defect, closing the gap between sensitivity and specificity scores, which balanced the testing method of the present Invention and proved the predictive accuracy to the middle to high ninety percent (90 %), as independently observed by medical physicians, verifying that the Applicant's Invention is substantially repeatable. Specification, p. 6. Therefore, the result found by this method Invention

is not speculative and would not require further undue experimentation to produce concrete results. The utility of the Invention is specific, substantial, and credible, as confirmed in the related art applications in Hamlin, et al. MPEP §2107.

As noted in the Specification, failure in predicting outcome for treatment aimed at pain relief has been one of the most costly problems facing the health care delivery system today. Specification, p.1. Prior to the Applicant's invention there is almost no support in medical literature for psychological/psychiatric assessment as a reliable predictor of surgical outcome other medical treatment for the relief of pain. See Hamlin, et al. As set forth in the Specification, the present Invention specifically identifies and quantifies psychological problems and predicts, to a high statistical probability (i.e., demonstrating a substantial and credible utility and repeatability), the probability of patient pain relief, where symptoms do not correspond with diagnostic studies and/or physical symptoms. Hamlin, et al, at p. 258. A person of ordinary skill in the art would immediately appreciate why the Invention is useful based on the characteristics of the Invention, the properties and applications of the Applicant's method, as set forth. MPEP §2107.

The enablement concerns set forth in the Office Action stem from doubts as to whether the invention is capable of substantial repeatability. However, the Applicant's specification clearly does not lend credence to such doubts. In calling the enablement of disclosure into question, an Office Action has the burden of advancing acceptable reasoning inconsistent with enablement. *In re Strahilevitz*, 668 F.2d 1229, 1232, 212 U.S.P.Q. 561, 563-64 (CCPA 1982). Given the absence

of such reasoning in view of the disclosure in Applicant's Specification, the Applicant has established that the invention will function in the manner disclosed and claimed.

Applicant respectfully submits that Claims 1 and 2 are supported by either a specific and substantial asserted utility or a well-established utility, for the reasons set forth. Particularly with respect to the assertions by the Hamlin, et al article regarding the related art, it is readily apparent that the claimed invention has a well-established, practical utility, with immediate benefit to the public, and this article rebuts the basis or logic of the argument of no specific and substantial credible utility under 35 U.S.C. §101 and §112.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1 and 2 are being rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the Invention. Specifically, claim limitations 1(c) and 1(d) are rejected for failing to provide for alternative limitations. Applicant has made the following amendments:

Applicant has overcome the rejections of claim 1 and 2 by amending and rewriting independent claim 1 by deleting in claims 1(c), lines 11 and 12, and 1(d), lines 16 and 17, the words *"at least"*, thereby eliminating the alternative expression.

Additionally, Applicant has made the following amendments:

Applicant has amended claim 1(a), line 5, to correct a grammatical error, deleting the word *"perceptional"* and inserting the word *"perceptual"*.

Applicant has amended claim 1 (g), (i), and (j) page 26, lines 4, 10 and 13, deleting the word *"the"*, and substituting the word *"a"*, where there is no antecedent basis for the recitation.

Applicant has amended claim 1 (h), page 26, line 8, inserting the word *"the"*, where there is an antecedent basis for the recitation.

Applicant has amended claim 1 (k), (m), (n), and (o), on pages 26 and 27, providing for separate method steps starting with the word *"determining"*. Claim 1 (l), (m), (n), (o), (p), (q), pages 26 and 27 are re-lettered respectively to reflect claim 1 as amended., to provide for the separate method steps.

Applicant has amended claim 2 (a), page 28, line 5, to correct a grammatical error, deleting the word *"predicted"* and inserting the word *"predict"*.

Applicant respectfully submits that the foregoing amendments to Claim 1 overcome the rejections under 35 U.S.C. §112 cited in the Office Action.

Rejection under 35 U.S.C. §102

Claims 1 and 2 are being rejected under 35 U.S.C. §102(b) as being anticipated by the Hamlin, et al article, cited above. Applicant respectfully submits that the Hamlin article does not anticipate Claims 1 and 2 for the following reasons.

In order to support an anticipation rejection, the reference must disclose the claimed invention. *Innovative Scuba Concepts Inc. v. Feder Indus.*, 819 Fed. Supp. 1487, 22 U.S.P.Q 2d 1254, 1263 (D. Colo. 1993). The description in a prior art reference, such as a printed publication, must enable a person of ordinary skill in the art not only to comprehend the invention but also to make it. *Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F. 2d 659, 665, 231 U.S.P.Q. 649, 653 (Fed. Cir. 1986), *cert. denied,* 480 U.S. 933 (1987). In short, the prior art reference must teach.

The assertion in the Office Action that the prior art reference, Hamlin, et al, adequately describes the subject matter to place it in the public domain is not reasonably supported. The prior art reference must disclose each element of the claimed invention arranged as in the claim. *Lindermannn Maschinenfabrik GmbH v. American Hoist & Derrick Co.,* 730 F. M2d 1452, 221 U.S.P.Q. 481, 485 (Fed. Cir. 1984), *and, RCA Corp. v. Applied Digital Data Sys., Inc.*, 730 F.2d 1440, 221 U.S.P.Q. 385, 388 (Fed. Cir. 1984). However, the prior art reference cited in the Office Action does not inherently, or overtly, disclose all of the elements of the Invention. The prior art reference is lacking or missing specific features and structure of the claimed invention. As well, claims 1 and 2 recite

specific structure used to implement the method. The reference is clearly missing certain elements of the claims.

When asked, as recited in Hamlin, et al, to explain the Paindex® test, the Applicant is shown therein to explain merely that "the test probability predictive equations were developed by using logarithm regression equations of the [MMPI] items to determine which factors had a strong relation to outcome." Hamlin, et al, p. 259. The cited reference is silent as to the elements of the method of the present invention. The method was not disclosed.

Hamlin, et al sets out an assessment of the predictive capability of the earlier work of the Applicant. Hamlin, et al, pp. 259-261. The position of the Office Action rests on an assertion that Applicant's invention is the same as that being disclosed by Hamlin et al. However, Hamlin et al does not disclose the elements of the Invention. There is no discussion in Hamlin, et al about selecting responses from 3 specific validity factors and 6 specific clinical factors, as set forth in Claim 1(c) and (d). The Hamlin, et al articles does not disclose that a carelessness factor raw score is used to assessing errors in the test. Claim 1(f). Among other omissions, the Hamlin, et al article does not disclose that the raw scores from certain the clinical factors are adjusted by a percentage of the defensiveness factor raw score. Claim 1(g). The Hamlin, et al article does not disclose preserving a certain set of raw scores, standardizing certain scores from certain clinical factors, applying a set of certain scoring rules and determining scoring values. Claim 1(i), (j), (k), (m), (n), and (o). The Hamlin, et al article makes no mention of the ego integrative defect clinical

factor and its use in the summation of the scoring values to produce a single pain index score. Specification and Claim (l), (p), and (q). Finally, the Hamlin, et al article does not disclose the relationship that is applied for the pain index score and the probability equation score. Claim 2.

The claims of the present invention are patentably distinguishable from the prior art. *See* MPEP 706.02(b). Applicant respectfully submits hereby that the Hamlin article does not anticipate Claims 1 and 2 for the reasons set forth.

CONCLUSION

For all the reasons advanced above, the Applicant respectfully submits that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

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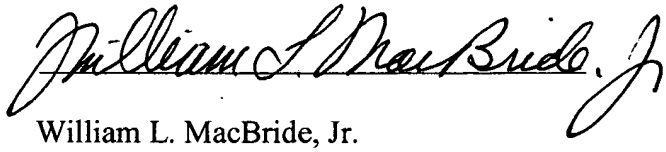

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